510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is:_____.

1. **Submitter's Identification:**

HealthInterlink, LLC
2323 S. 171 Street, Suite 202, Omaha, NE 68130
Tel: 402-718-8824
Fax: 402-519-2173

Date Summary Prepared: **October 1, 2013**

2. **Name of the Device:** HealthInterlink Beacon

3. **Common or Usual Name:** Remote Patient Monitoring System
Regulation No. 21 CFR 870.2910
Product Codes: DRG, DXN, FRI, FLL, NBW, DQA, JQP

4. **Predicate Device Information:**

K112559	MEDAPPS 2.0 REMOTE PATIENT MONITORING SYSTEM
K112858	GENESIS TOUCH SYSTEM
K122285	TABLET COMMANDER
K103276	INTEL HEALTH GUIDE EXPRESS

5. **Device Description:**

The HealthInterlink Beacon is a software application. Once installed on a commercially-available device, the HealthInterlink Beacon software uses standard communication protocols to exchange information with other medical devices (peripherals). Data collected from the medical devices is transmitted to a server database for review by a caregiver. The HealthInterlink Beacon software has a user interface which allows the patient and caregiver to communicate using methods which include questions, answers, and messages.

HealthInterlink Beacon is not intended for emergency use or real-time monitoring.

6. Intended Use:

The HealthInterlink Beacon device is for use by patients to collect and transmit general health information, physiological measurements such as blood pressure, temperature, weight, glucose and SpO2 using commercially available FDA cleared wireless medical devices designed for home use, and other data between themselves and a caregiver.

The HealthInterlink Beacon makes no diagnosis. Clinical judgment and experience are required to check and interpret the information transmitted. HealthInterlink Beacon is not intended as a substitute for medical care.

7. Comparison to Predicate Devices:

	Honeywell HomMed Genesis Touch K112858	CardioCom Tablet Commander K122265	Intel Health Guide Express K103276	MedApps 20 Remote Patient Monitoring System K112559	HealthInterlink Beacon
Indications for Use	Enables healthcare providers to monitor and manage conditions of patients remotely	Same	Same	Same	Same
Intended Use	Telemedicine System	Same	Same	Same	Same
Intended Users	Home users and healthcare providers	Same	Same	Same	Same
Site of Use	Healthcare related environment or home	Same	Same	Same	Same
Data Collection Software	LifeStream Management Suite	Cardiocom's OMNIVISOR Management System	Intel Care Management Suite Software	MedApps Proprietary Software	HealthInterlink Beacon Software
Data Collection Software Functionality	Transmit data from Sensor devices to Central Database	Same	Same	Same	Same
Communication method of hub with Central Server	Via public telecommunications network	Via public telecommunications network	Via DSL or Phone Line Connection	Via Embedded Cellular Technology	Via public telecommunications network
Types of sensors which can be interfaced (wired or wirelessly) to receiver hub	Medical Devices designed for Home use: Scale, Blood Pressure, Pulse Ox, Thermometer	Medical Devices designed for Home use: Glucose, Scale, Blood Pressure, Pulse Ox, Peak Flow	Medical Devices designed for Home use: Glucose, Scale, Blood Pressure, Pulse Ox, Peak Flow	Medical Devices designed for Home use: Glucose, Scale, Blood Pressure, Pulse Ox	Medical Devices designed for Home use. Glucose, Scale, Blood Pressure, Pulse Ox, Temperature, Spirometer
Implementation method of collecting data from sensors	Short range radio system using Bluetooth (Manual entry for Thermometer)	Short range radio system using Wireless (Bluetooth) and Wired (tethered) cables	Short range radio system using Wireless (Bluetooth) and Wired (tethered) cables	Currently using Wired (tethered) , cables (USB), Smart Cables	Short range radio system using Bluetooth, manual entry, Text/Interactive Voice Response
Sensor Software	Sensor Software unchanged	Same	Same	Same	Same
Connectivity	Short range radio system using Bluetooth	Short range radio system using Bluetooth and Wired (tethered) cables	Short range radio system using Bluetooth and Wired (tethered) cables	Wired (tethered) cables Future capability to use Bluetooth dongles	Short range radio system using Bluetooth
Communication method of hub with devices	Short range radio system using Bluetooth	Short range radio system using Wireless (Bluetooth) and Wired (tethered) cables	Short range radio system using Wireless (Bluetooth) and Wired (tethered) cables	Currently using Wired (tethered) cables	Short range radio system using Bluetooth
Communications Protocol	Wireless (Bluetooth) V20	Wireless (Bluetooth) V20 & Wired (Tethered)	Wireless (Bluetooth) V20 & Wired (Tethered)	Wired (Tethered)	Wireless (Bluetooth) V20 and Wireless (Bluetooth) V40
Communication Frequency	Bluetooth: 2402 to 2480 GHz	Bluetooth: 2402 to 2480 GHz	Bluetooth: 2402 to 2480 GHz	GSM: 850/900/1800/1950	Bluetooth 2402-2480 GHz
Power Source	Wall power plug (120 VAC/50-60)	Same	Same	Same	Same
Visual Feedback/Display	On devices and hub, monitors connected to central server	On devices and hub, monitors connected to central server	On devices and hub, monitors connected to central server	HealthAIR uses LED light indicators	On devices and hub, monitors connected to central server
Communication with Patients	On screen display	On screen display	On screen display	Audio/visual feedback from LED light indicators & audio tones; Interactive Voice Response (IVR) system for patient contact	On screen display, Text/Interactive Voice Response

8. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

The submitted HealthInterlink Beacon system has undergone design control verification and validation testing. HealthInterlink Beacon validation testing includes testing of all executable code and functionality and confirmation that all identified risks have been adequately addressed by software functionality, the user interface, documentation or user SOP. HealthInterlink Beacon system verification and validation activities as part of the design control process include testing of all Design Specifications (Design Control Inputs) based on risk analysis and Verification plans. HealthInterlink Beacon Verification Plan execution ensures the system works with each type of user accessory medical device (blood pressure monitor, scale, thermometer, glucose, and pulse oximeter) as part of the HealthInterlink Beacon system including integration to Beacon Clinical Care Access (CCA) backend software application. The output of these design control verification analysis documents for the HealthInterlink Beacon system shall meet its requirements and design specifications as intended. No new hazards to safety or effectiveness are presented by HealthInterlink Beacon, therefore, no clinical tests were conducted.

9. Discussion of Clinical Tests Performed:

No new hazards to safety or effectiveness are presented by HealthInterlink Beacon, therefore, no clinical tests were conducted.

10. Conclusions:

HealthInterlink considers the HealthInterlink Beacon to be equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 14, 2014

Healthinterlink, LLC
% Susan Goldstein-Falk
Official Correspondent
MDI Consultants, Inc.
55 Northern Blvd, Ste. 200
Great Neck, NY 11021 US

Re: K133252
Trade/Device Name: Healthinterlink beacon
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter and Reciever
Regulatory Class: Class II
Product Codes: DRG, DXN, FRI, FLL, NBW, DQA, JQP
Dated: January 29, 2014
Received: February 11, 2014

Dear Susan Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

Device Name

HealthInterlink® Beacon®

Indications for Use *(Describe)*

The HealthInterlink® Beacon® device is for use by patients to collect and transmit general health information, physiological measurements such as blood pressure, temperature,weight, glucose and SpO2 using commercially available FDA cleared wireless medical devices designed for home use, and other data between themselves and a caregiver.

The HealthInterlink® Beacon® makes no diagnosis. Clinical judgment and experience are required to check and interpret the information transmitted. HealthInterlink® Beacon® is not intended as a substitute for medical care.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Date:
2014.03.14
13:46:10 -04'00'
for Bram Zuckerman